

# **EXHIBIT C**

# BUTLER | SNOW

March 28, 2013

Via E-Mail [tcartmell@wagstaffcartmell.com](mailto:tcartmell@wagstaffcartmell.com)

Tom P. Cartmell, Esq.  
WAGSTAFF & CARTMELL, LLP  
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Re: Pelvic Mesh

Dear Tom:

This letter follows our meet and confer on Friday, March 22, 2013, regarding our objections to the 30(b)(6) Design Deposition notice. Set forth below are our responses to most of the issues we discussed on that call. In addition to the responses below, we sent you a letter earlier today that specifically addresses your request for "Standard Operating Procedures." Finally, as noted below, we are also continuing to work on some of the other topics we discussed during the March 22 phone call.

## **I. Moving the Deposition**

We have given you dates of April 9-10, 2013, for the deposition of Dan Smith in Morristown, New Jersey. You told us that Plaintiffs would not go forward with the deposition on these dates for three reasons: (1) New Jersey counsel were unavailable on those dates; (2) the supplemental production of Dan Smith's custodial file included 18,000 documents, which Plaintiffs are still reviewing; and (3) Plaintiffs wanted to continue to work through the objections we posed in regard to the design notice you informally provided us.<sup>1</sup> You also asked if Dan Smith would be available during the weeks of May 6 or May 13, 2013, preferring to avoid May 9-10, if possible.

We have discussed this issue with Dan Smith, and he is available on both May 9-10 and May 15-16, 2013. Because you asked us to avoid the 9<sup>th</sup> and 10<sup>th</sup>, we will plan for the deposition to occur on May 15-16, 2013, unless we hear differently from you. Thus, we are canceling plans to present Mr. Smith on April 9-10.

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<sup>1</sup> We understand that it is your position that you served this notice on us. However, we have confirmed that neither the Notice nor a Certificate of Service for this notice was filed with the Court. As we discussed on March 22, rather than debate the issue, we prefer to continue to try to reach a solution that balances your legitimate discovery needs with our legitimate interests in protecting our client from discovery that exceeds that permitted by the Rules.

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Tom P. Cartmell, Esq.  
March 28, 2013  
Page 2

## **II. Substantive Topics**

During the call we also met and conferred regarding some of the objections to the 30(b)(6) topics. I have summarized these discussions and our position below.

### **a. Topic a (SOPs)**

Topic “a” seeks testimony regarding “[t]he Standard Operating procedures (SOP) associated with design and development of the devices.” We objected as set forth in our Responses and have addressed this issue in the separate letter we sent you earlier today.

### **b. Topic b (Design History File)**

Topic “b” seeks testimony regarding “[t]he complete design history file for the Devices, including each component part of the file . . . .” We objected that this was overly broad, and it is our understanding that you now agree. It is also our understanding that you have reformulated this topic to seek testimony regarding the following: (1) what makes up the Design History File (“DHF”); (2) what are the component parts of the DHF; (3) the custodian of the DHF; (4) how the DHF is maintained; and (5) the Bates ranges for each DHF.

We will produce a witness to testify in regard to items 1-4 of the reformulated topic, but stand on our objection as to item 5. As we have discussed in our prior calls, we are more than willing to provide Plaintiffs with a written discovery response that identifies the Bates ranges of each Design History File to satisfy any concern you have about whether you have a “complete” file. However, we do not agree that it is an appropriate subject for a 30(b)(6) deposition to require a company designee to testify regarding the Bates ranges of particular documents. Mr. Smith, who will be our designee in regard to the DHFs, played no role in Bates stamping these documents. Notwithstanding this fact, if the DHF was a smaller document, we would have no problem with you showing the document to Mr. Smith and asking him to confirm that it is the complete document (as we did with Susan Lin and the 510(k) submissions). But we do not believe it is an appropriate method of discovery for you to question Mr. Smith about the “completeness” of a document for which he bears no personal responsibility in producing and which is far too voluminous for him to personally verify the accuracy of the produced copy. Again, we are willing to provide you with this information in a different form.

### **c. Topic c (Members of Product Development Teams)**

Topic “c” seeks testimony regarding the “Members and procedures of the Product Development Team for the Devices.”

We have previously explained to you why we believe this is an inappropriate topic for a 30(b)(6) deposition in this context. We maintain that objection for the following reasons.

Tom P. Cartmell, Esq.  
March 28, 2013  
Page 3

First, this is a vague topic that will be subject to the interpretation of an individual witness, and various witnesses may consider the same individual to be "on" or "not on" the design team for a device, particularly in regard to witnesses that had a tangential role.

Second, even if you ignore that distinction and reformulate this topic to seek the identity of every person who worked on each of the projects, we still object because: (a) this would be an inappropriate topic for a 30(b)(6) deposition due to the significant number of individuals that worked on the development of each product; and (b) we have already produced documents that set forth the individuals who worked on the development of these products.

As an example, in regard to the products developed most recently (e.g. TVT Abbrevio and Exact), more than thirty individuals were involved in the design and development. No witness could be expected to remember the identity of so many individuals for so many products over so many years.

In regard to our prior productions, we have produced the DHFs of each of these devices. The names of the various individuals who worked on these projects are included within the DHFs. Specific documents that list individuals working on the project include the Design and Development Plan, Team meeting minutes, and lab reports. Thus, you are equally able to ascertain the identities of the individuals who worked on these projects.

**d. Topic h (Bench testing, porosity testing, particle loss, fraying, degradation)**

Topic "h" seeks testimony regarding the "specifics of all testing related to the Devices . . ." We have previously informed you that this will require the testimony of multiple witnesses, and it is our understanding that the only remaining issue is your request that we identify these witnesses. Obviously, under the Rules, we are permitted to select designees and to change those designees if appropriate. However, we are willing to tell you that, at this time, we intend to designate the following individuals to address this issue: (1) Dan Smith, from a design perspective; (2) Pete Hinoul, from a medical perspective; and (3) Tom Barbolt from a pre-clinical perspective. If this changes, we will let you know immediately.

**e. Topic i (All project names of TVT)**

Topic "i" seeks testimony regarding all project names for all TVT Devices. We have previously explained why we believe this is an inappropriate topic for a 30(b)(6) deposition in this context, and we continue to maintain that objection. However, in an effort to compromise, we will, in advance of the deposition, provide Plaintiffs with a list of all project names of which we are aware for the TVT Devices identified in your notice. Dan Smith has recently reviewed this list and will testify that, to the best of his knowledge, it is a complete list.

Tom P. Cartmell, Esq.  
March 28, 2013  
Page 4

**f. Topic s (Patents)**

Topic “s” seeks testimony regarding “any patents related to the Devices and their predecessor mesh products.” We objected that this was overly broad. During our March 22<sup>nd</sup> call you indicated that what you were really seeking was: (1) who holds the patents; (2) the description from the patents; and (3) “design and development issues” for each patent.

We are willing to provide you the identity of the holder of the patent and the description of the patent. However, we maintain our objection regarding the “design and development issues” for each patent. It is simply impossible for a witness to testify regarding this topic without further information. We suggest that we provide you with the information we are agreeing to produce, that you review that information, and that you ask Dan Smith at the deposition about the design and development issues related to any of the patents for which he has personal knowledge. If there are additional issues you feel need to be addressed on this topic, we suggest that it be done through subsequent fact witness depositions, not in the context of a 30(b)(6) deposition. We are more than willing to continue discussing this topic if you have an alternate solution or can provide greater guidance on what you are seeking for “design and development issues.”

**g. Topic t (Identity of Consultants and Compensation)**

We are still making inquiries regarding this proposed topic and will follow up with you as soon as we can.

**h. Topic v (Monitoring of Literature re TVT)**

We are still making inquiries regarding this proposed topic and will follow up with you as soon as we can.

**i. Topic ii (sic)(Budget/Finances)**

We are still making inquiries regarding this proposed topic and will follow up with you as soon as we can.

**j. Topic jj (Identity of Consultants)**

We are still making inquiries regarding this proposed topic and will follow up with you as soon as we can.

**k. Topic kk (Manufacturing Process re heating/extrusion/etc.)**

We are still struggling with this topic because we do not understand what level of detail you are seeking. When we discussed this on the call on March 22<sup>nd</sup>, you stated that you want to

Tom P. Cartmell, Esq.  
March 28, 2013  
Page 5

know the process by which the Prolene mesh is manufactured, woven, tested, and sterilized, and that you would seek similar "type" information regarding the tools that accompany each device.

Dan Smith is very knowledgeable about the manufacturing processes in general and will be prepared to discuss this topic at a high level. However, if you choose to drill down on a particular topic in greater detail, we may have to identify additional witnesses to address those particular topics. Based upon the guidance you have given us to date, that is all we can do at this point.

**I. Topic z (Identity of the Person involved with "Original Decision" to develop TVT products)**

We objected to this topic and maintain that objection. Simply put, Ethicon is a corporation, not an individual, and the phrase "original decision" is vague. Notwithstanding that objection, Ethicon will present a witness to testify regarding this topic to the best of his or her ability, given the problems identified in the topic.

Please let us know if you have any questions or would like to discuss further.

Sincerely,

BUTLER, SNOW, O'MARA, STEVENS & CANNADA, PLLC



Chad R. Hutchinson

CRH:ljg

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